FROM CDC FILES

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BASIC

DATE: July 28, 1970

TO: Dr. David J. Sencer, Director, Center for Disease Control

FROM: Anne R. Yobs, M.D.

SUBJECT: Untreated Syphilis in Humans (Tuskegee Study)

The subject project is unique in medical and United States Public Health Service history. Through the years considerable financial and staff resources have been expended in its establishment and continuation. With the passage of time there have been staff changes and losses of patients through death and other causes. More importantly, there have been changes at the program level in attitude, in level of interest, and in sensitivity to (potential) criticism.

I recommend, therefore, that this study be closed and followed by the publication in monograph form of an authoritative evaluation of findings and results. Such a monograph should include all research which has been an outgrowth of the study, as well as discussions of clinical findings, pathogenesis of the disease process and special clinical tests performed at times as part of the patient evaluation. Ample material for such a publication is available on such topics as project history, importance of clinical history, physical findings in various stages, diagnostic tests, radiologic findings, cardiovascular disease evaluation and progression, central nervous system disease, neuroophthalmic findings, effects of adequate-inadequate treatment, anatomical pathology, etc.

Chapters in this monograph should be invited from experts who are well-versed in techniques and concepts of modern clinical medicine and of equal importance interested in and knowledgeable about the disease Syphilis. Authors should be chosen selectively and appropriately remunerated to assure completion of contributions and highest quality of the final document. Library and graphic arts assistance should be made available to the authors.

Such an end to this work would be a valuable contribution to medicine and to public health today and this recognition of the project's value would help quiet critics. If such an approach is elected, action should be initiated immediately before staff continuity has been totally lost. At any rate, a definite decision regarding continuation of this project should be made and implemented.

Anne R. Yobs

Anne R. Yobs, M.D.
Medical Officer

Tuskegee Study

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

August 5, 1970

Tuskegee Study

Chief, Venereal Disease Branch

1. Currently we are locating all patients in the Tuskegee Study who have been lost to follow-up. Probably within the next several months we will have located and given them a medical examination and evaluation. Periodic examinations have been done from time to time, but very little planning was ever done for overall continuity. In addition, a number of articles have been written detailing special interests of the authors. Very few, if any, have given an overall perspective of the study.

2. At the present time, except for one statistical clerk, we have no one working full time on the study. The study is coming to a natural conclusion with the death of many of the patients. Consequently, a full-time medical investigator should be hired to coordinate the final stage of this longterm study. This coordinator should be a physician and have his boards in [illegible] cardiology, or dermatology with a [illegible] in the [illegible].

3. This study is too large an undertaking for anyone in the office of the Chief to supervise and coordinate detailed activities on a part-time basis. If the study is to be brought to a conclusion, data retrieved for our records, and results reported to literature, a full-time person is mandatory. He would be assigned to the office of the Chief under Special Studies and would coordinate the present administration of the Tuskegee Study as well as review all the collected data. He would also edit a monograph that would report all the findings of the study in [illegible].

4. To conclude the study with a monograph would require at least three to four years of continuous work by the coordinator. He would also need a secretary and clerk statistician to assist him. Dr. [illegible] has agreed to give consultation on a part-time basis. Although such a monograph would appear to be costly to produce, I doubt that the total cost would be more than $150,000 over a three to four year period.

5. The monograph would be a final report on the Tuskegee Study and would require the services of specialists from many disciplines to review, interpret, and report the results. Consultants outside the PHS could be called on to write chapters on specific aspects of the study, i.e., since we have a large volume of data on the cardiovascular findings on patients in the study, a chapter could be devoted to the cardiovascular findings in untreated syphilis. Another chapter could be written by a neurologist giving the neurological findings, etc.

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6. As the study is now losing patients very rapidly and many individuals who have had interest in the study in the past are wavering or no longer can make a contribution, it is somewhat of an exigency that a decision be made on this matter in the near future.

7. If we plan to continue the [illegible] in a scientific manner, we should [illegible] so the information will be a significant contribution to medical literature.

Arnold L. Schroeter, M.D.
Chief, Clinical Research

cc:
Dr. James
Dr. Rudolph

ALSchroeter/vs

August 24, 1970

Untreated Syphilis in Humans (Tuskegee Study)

Anne R. Yobs, M.D.

Thank you for your memorandum on the Tuskegee Study. I share some of your concern about the direction things are taking. We are in the process of trying to locate all the persons who have been in the study population utilizing some of the talents of the Tuberculosis Research Program.

I am asking, by a copy of this memorandum to Dr. Millar, that he give serious consideration to what can best be done to document the very substantial body of knowledge that has arisen out of the project. We will keep you informed of this.

Thank you again for your continued interest in this study.

David J. Sencer, M.D.
Assistant Surgeon General
Director, NCDC

cc: Director, State & Community Services Division

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION

Date: September 10, 1970

Reply to Attn of:

Subject: An analysis of the current status of the Tuskegee Study

To: William J. Brown, M.D.
Chief, Venereal Disease Branch

1. In recent years the Tuskegee Study has become an increasingly emotionally charged subject. This aura has in large measure prevented a rational appraisal of the situation. It is hoped that these remarks will aid in restoring our prospectives and lead to a reasonable course of future action.

2. Priority - Resources must follow priorities. While some medical knowledge has been gained from this study its volume and quality has been less than gleaned from the preceding Boeck-Bruusgaard study. This is largely because effective and undocumented treatment has been given to the vast majority of patients in the syphilitic group. Most received this therapy in the "happenstance" manner while under treatment for other conditions. The impact of this inadvertent treatment will be almost impossible to assess, but without question the course of untreated syphilis (which the study was supposed to have delineated) has been radically altered. This is not to suggest that some contributions to medical knowledge do not yet lurk in the information gathered to date. However, it must be fully realized that the remaining contribution from this study will be largely of historical interest. Nothing learned will prevent, find, or cure a single case of infectious syphilis or bring us closer to our basic mission of controlling venereal disease in the United States.

3. Probably the greatest contribution that the Tuskegee Study has made and can continue to provide has been documented sera for study in our laboratory. Without these sera the problem of evaluating new serologic tests becomes much more difficult and the results less certain. In a great measure the development and our endorsement, of the FTA-ABS test rested on Tuskegee sera. The collection of future specimens hardly requires a special unit for that purpose.

4. To point up how obtunded the medical findings are currently one must only look to the special study carried out in 1967 by Dr. J. Lawton Smith. We permitted him to study these patients, but insisted on a "blind" study so he would not know who were syphilitic and who were controls. All available patients were rather elaborately studied for neurologic and ophthalmologic defects. When Dr. Smith presented his clinical findings we broke the code. Absolutely no correlation was discovered between the pathology uncovered in his study and the status of the patients.

5. All of this simply serves to point out that neither major medical revelations nor program benefits are likely to be forthcoming irregardless of who supervises the study, and thus the overall priority of the Tuskegee Study from these viewpoints is relatively low.

6. Moral Obligation - Any question of termination hinges upon an obligation to the remaining syphilitic patients. This is both an implied and expressed obligation. The long continued assignment of Mrs. Laurie and now Mrs. Kennebrew to Tuskegee demonstrates our good faith and sincerity. The annual examination of survivors and referral of those with significant physical findings also clearly demonstrates our position and good will. Several recent pieces of correspondence indicate that termination is now desirable since many of the patients are now dead or that the deaths of those remaining will bring the study to a natural termination within the next few years. Certainly we are obligated to maintain our present level of observation as long as a significant number of patients remain alive.

7. A point may be reached where the number of survivors no longer justifies continued surveillance, but this might expose the program to justifiable criticism on grounds of the moral issue. What number of survivors would justify such a decision?

8. A more definite answer can be made concerning natural termination. One merely needs to know the current number of survivors, their average age, and have access to a life table for non-white males to definitely determine the number who will be living for any future year. Currently 149 syphilitics are alive and their average age is 71. In five years, 101 can be expected to still be alive. In 1980, sixty-eight of the syphilitics will still be living. In the years that follow the annual mortality will probably be no greater than 9-10 percent so that approximately 25 individuals may reasonably be expected to survive yet another decade (1990). This exercise simply points out that natural termination in the forseeable future is an unlikely event.

9. It is also suggested that a lack of continuity on the part of VD personnel is a valid excuse for termination. I would like to point out that this study has not had a fulltime person (other than Nurse Laurie) handling this study for a great many years. Periodically medical officers have become interested or were assigned for short periods to the project, but there has been very little medical continuity since the inception of the study. It is true that Mrs. Price has handled the record keeping for many years, but this was only a small part of her duties. She is still readily available as a consultant should questions concerning the records arise. In essence then, there has long been a lack of medical continuity and the need for this now is debatable at best.

10. Due to our present financial duress it hardly seems feasible to commit $150,000 over a three or four-year period or even hire a GS-14 pathologist to oversee the study. It has also been suggested that a summary monograph obstensively authored by appropriate experts be prepared. This raises several questions. Why outside experts, who have not been involved in the study? Such experts may very well prefer not to be associated with this study because of its sensitive nature. In any event there remains very little expertise on late syphilis.

11. More importantly, what would be the value of an elaborate and expensive monograph? The "green book" certainly adequately covers the pertinent aspects of late syphilis. Distribution of such a monograph might well cause more harm than good to the program.

12. A much more realistic approach would involve the preparation of a series of "in-house reports." Any findings of special interest or importance might then be published in appropriate journals as has been done in the past.

13. In summary, three distinct courses of action appear to be open:

(1) The study may be terminated. This is clearly not justified from the foregoing discussion. In fact the assignment of a new nurse already indicates our dedication to this study and its subjects.

(2) The study may be continued along its present lines with periodic clinical observation and serologic surveillance. On occasion the publication of any new significant finding may be considered. This can be handled by the present staff in clinical research with occasional supplementation by VDRL or VD Branch medical officers.

(3) A special unit with a fulltime director may be created. The costs, value and long term nature of this option have been discussed.

14. In my opinion, when all factors are considered, the second option appears to be the wisest course of action.

James B. Lucas, M.D.
Assistant Chief
Venereal Disease Branch
State and Community Services Division